

REMARKS

After entry of this amendment, claims 1-13, 16-21, 25, 27-30 and 32 are pending, of which claims 1, 6-13, 16-21, 25 and 27-30 are withdrawn. Claim 31 was cancelled without prejudice or disclaimer. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. The amendment to claim 2 finds further support in the specification, for example, at pages 20-21, paragraph [0063.0.0.0], at page 77, line 10, at page 81, line 17, and Table 1 at page 174. No new matter has been added.

Applicants respectfully request entry of the above claim amendments as it is believed to put the claims in condition for allowance or, alternatively, in better form for consideration on appeal. Thus, entry under 37 CFR §1.116 is correct.

Rejection under 35 USC § 112, first paragraph

Claims 2-5 stand rejected and claims 31-21 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description rejection. Applicants respectfully disagree. However, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and further clarify the method, nucleic acids, and fine chemicals.

The Examiner appears to base the rejection on an alleged lack of description of a genus which recited 70% identity or hybridization to SEQ ID NO: 2. In light of the amendments, the basis for the rejection is no longer believed to be applicable. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 USC § 112, second paragraph

Claims 2 and 3-5 stand rejected and claims 31-32 are rejected under 35 U.S.C. § 112, second paragraph, for allegedly being incomplete for omitting an essential step. Applicants respectfully disagree. However, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and further clarify the method, nucleic acids, and fine chemicals.

The Examiner alleges that claim 2 omits a step by which the increasing or generating of expression is accomplished. In light of the amendments, the rejection is believed to be rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 102(b)

Claims 2, 3 and 5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Qadota *et al.* (hereinafter “Qadota”). Applicants respectfully disagree.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). “We thus hold that unless a reference discloses within the four corners of the document not only all the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim, it cannot be said to prove prior invention of the thing claimed and, thus, cannot anticipate under 35 U.S.C. § 102.” *Net MoneyIN Inc. v. VeriSign Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

The Examiner alleges that Applicants assessment of claim 2 is incorrect and alleges that Qadota anticipates the claim because a protein comprises amino acids. Applicants disagree that Qadota anticipates the claim; nonetheless, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and further clarify the method, nucleic acids, and fine chemicals.

Qadota does not teach the claimed process nor the fine chemicals as now claimed. Because Qadota does not disclose all the claim limitations, Qadota does not anticipate the claims. In light of the amendments, the rejection is believed to be rendered moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claim 4 is rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Qadota in view of Monaghan *et al.* (hereinafter “Monaghan”). Applicants respectfully disagree and traverse for the reasons already of record and additionally for the following reasons.

The Examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Further, to support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994)

The Examiner alleges that Applicants assessment of claim 2 is incorrect and alleges that Qadota does teach a process for the production of the fine chemicals which includes a protein, because a protein comprises amino acids. Applicants disagree; nonetheless, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and further clarify the method, nucleic acids, and fine chemicals.

The Examiner relies on Qadota for allegedly teaching increasing or generating the expression of SEQ ID NO: 1 in yeast and recovering a free or bound fine chemical, i.e., a protein. The Examiner acknowledges that Qadota does not teach the limitations recited in claim 4, but relies on Monaghan for such teaching. As amended, the claims now relate to the production of at least one fine chemical selected from the group consisting of amino acids, carbohydrates, vitamins, organic acids, fatty acids, and carotenoids. Qadota does not teach a process for the production of such fine chemicals.

The Examiner relies of Monaghan for teaching a process for making and selecting mutants of *Saccharomyces cerevisiae* and thus the steps of claim 4. However, Monaghan does not remedy the deficiencies of Qadota. Neither Qadota nor Monaghan, alone or in combination, teach or suggest production of the fine chemicals as now claimed. Because Qadota and Monaghan, alone or in combination, do not teach or suggest all the claim limitations, a *prima facie* case of obviousness has not been established.

The Examiner refers to the Office Action dated July 28, 2008 for the reasons for the obviousness rejection. In the Office Action dated July 28, 2008, the Examiner alleges that it would have been obvious

“to make and select mutants of *Saccharomyces cerevisiae* that have an increased activity or expression level of *Saccharomyces cerevisiae* RHO2 protein, given that the RHO2 protein and coding were known at the time the invention was

made (as evidenced by Qadota H. et al.), and given that methods for making and selecting mutants were well established in the art at the time the invention was made (as evidenced by Monaghan E. et al.). One skilled in the art would have been motivated to do so in order to functionally characterize the *Saccharomyces cerevisiae* RHO2 protein.” (Office Action at page 12).

A statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levensgood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See MPEP § 2143.01 IV. “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006) (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements ***in the way the claimed new invention does.***”) (emphasis added). Furthermore, the Examiner cannot selectively pick and choose from the disclosed parameters without proper motivation as to a particular selection. The mere fact that a reference may be modified to reflect features of the claimed invention does not make the modification, and hence the claimed invention, obvious unless the prior art suggested the desirability of such modification. *In re Mills*, 916 F.2d 680, 682, 16 USPQ2d 1430 (Fed. Cir. 1990); 16 *In re Fritch*, 23 USPQ2d 1780 (Fed. Cir. 1992). Thus, it is impermissible to simply engage in a hindsight reconstruction of the claimed invention where the reference itself provides no teaching as to why the applicant’s combination would have been obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

The modifications proposed by the Examiner appear to substitute the Lcb1/Lcb2 gene products for the Rho2 gene products of Qadota in the method of Monaghan, without any explanations or rationale for such substitutions. Simply stating that because both the method and the protein were known, it would be obvious to use the method of Monaghan for expression of

the protein disclosed in Qadota, lacks the specificity to support a legal conclusion of obviousness. The Examiner alleges that there does not have to be a connection between Rho2 and Lcb1/Lcb2 to render the claimed invention obvious. *KSR* still requires “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does.*” Because the requisite explanation or rationale has not been provided, a *prima facie* case of obviousness has not been established for this additional reason. Furthermore, because nothing in the references suggests to one of skill in the art the desirability for the substitution or combination suggested by the Examiner, Qadota and Monaghan are not combinable.

Even assuming *arguendo* the references were combinable and that such substitutions were made, because the references do not teach or suggest all the limitations of the present claims, the resulting process would still not arrive at the process for production of the fine chemicals as presently claimed.

For at least these reasons, reconsideration and withdrawal of the obviousness rejection is respectfully requested for the independent claims and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

CONCLUSION

In view of the above remarks and further in view of the above amendments, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications, if necessary.

Accompanying this response is a petition for a one month extension of time to and including August 3, 2009 to respond to the Office Action mailed April 3, 2009 with the required fee authorization.

No further fee is believed due. However, if an additional fee is due, the Director is authorized to charge our Deposit Account No. 03-2775, under Order No. 12810-00197-US from which the undersigned is authorized to draw.

Respectfully submitted,

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